

July 23, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.80

Subject: Distributor Labels

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum clarifies Center for Veterinary Biologics (CVB) criteria for review of distributor labels and gives licensees, permittees, and applicants guidance for drafting labels for review by CVB under 9 CFR 112.4(c) and 112.5(c).

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 800.80 dated December 3, 1991.

III. BACKGROUND

CVB reviews and approves all labels as required by 9 CFR 112.5(c) to ensure compliance with current requirements. Requirements for distributor labels in 9 CFR 112.4(c) prohibit label variations that appear false or misleading or which could indicate that the distributor is the manufacturer of the product or is operating under the license number shown on the label.

IV. GUIDELINES

A. Changes in the Distributor's Name and Address

Once CVB has filed a distributor label for a product, firms are permitted to make changes in the distributor's name and address without submitting a separate label for each new distributor. The approved labels and inserts on file with APHIS should otherwise be identical to the labels and inserts used by the firm for their final product. Any other change on the label regarding size, shape, coloring, shading, wording, font, print boldness, print quality, text arrangement, and trade name requires a separate submission for review and approval.

B. Presentation of Names and Addresses

Arrange the names and addresses of the manufacturer and distributor on distributor labels in a manner that gives equal or greater emphasis to the manufacturer compared with the distributor.

1. *Position on the Label* - Position the complete names and addresses of the manufacturer and distributor side by side or stacked one above the other on the same section of a label panel with the manufacturer's name and address listed first.

2. *Location on the Label* - If only one name and address can fit on the front label panel, place the manufacturer's name and address on the front panel and the distributor's on the back panel.

3. *Other Aspects of the Label* - All other aspects of the label must give equal or greater emphasis to the manufacturer. These aspects include, but are not limited to, logo, size, shape, coloring, shading, font, print boldness, text arrangement, and print quality.

C. Trade Names

1. *Selection and Use* - Select and use trade names according to Veterinary Services Memorandum No. 800.76.

2. *Review Required Before Use* - Place each trade name and any variation of a trade name on an appropriate label and submit this label to CVB for review and filing prior to use.

/s/ Thomas E. Walton for

Alfonso Torres
Deputy Administrator
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